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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/828,477 | 04/20/2004 | Swee Hin Teoh | NUS-8 DIV I | 4933 |
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| 04/29/2009 | | | | |
| EXAMINER | | | | |
| WOODWARD, CHERIE MICHELLE | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1647 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 04/29/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/828,477

Applicant(s)

TEOH ET AL.

Examiner

CHERIE M. WOODWARD

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40, 43, 44, 46, 48 and 59-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40, 43, 44, 48, 46, and 59-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

1. Applicant's Response, filed 13 January 2009, is acknowledged and entered. Claims 1-39, 41, 42, 45-47, 49-55, 57, and 58 have been cancelled by Applicant. Claims 40, 43, 44, 48, 56, and 59-64 are pending and under examination. In light of the new art cited below, this Office Action is NON-FINAL.

Response to Arguments

Objections/Rejections Withdrawn

2. The rejections of claims 59 and 62 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendments.
3. The objection to claim 40 because of a misspelling is withdrawn in light of Applicant's amendment.
4. Rejections over cancelled claims 50, 51, 57, and 58 are moot in light of the cancellation of these claims. However, to the extent the limitations set forth in these now cancelled claims have been incorporated by Applicant into other claims under examination, new rejections, necessitated by amendment, may be held.
5. The rejection of claims 40, 43, 44, 48, 56, and 59-64 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in light of Applicant's amendments.

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1647

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 40, 43, 44, 48, 50, 51, and 56-64 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al., US Patent 6,280,478 (28 August 2001), benefit to 4 January 1999), Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994), and Jang et al., US Patent 6,129,872 (10 October 2000, benefit to 29 August 1998), as evidenced by Kuslich, US Patent 5,549,679 (27 August 1996), for the reasons of record and the reasons set forth herein.

Applicant argues that although the '680 patent does not provide a suggestion or motivation for triangular pores or five-sided polygonal pores having the recited degrees of orientation (Remarks, p. 7). Applicant argues that permutations of the shape of the pore, size of the pore, depth of the pore, and repeatable patterns of the pore are "infinite and hence create a huge amount of possibilities" (Remarks, p. 7). Applicant argues that a determination of these factors can only be made after careful consideration and that it would not be obvious to select the structures, as recited, in the claimed apparatus (Remarks, p. 8). Applicant argues that the '680 patent only teaches general shapes and does not teach the instantly claimed microarchitecture (Remarks, p. 8). Applicant argues that the '872 patent only describes how the CAD model simulates a structure, but that this teaching does not actually teach a structure having lay-down patterns forming triangular pores or five-sided polygonal pores (Remarks, p. 8). Applicant states that the instant inventor "submits that the CAD model employs the use of unstructured triangulated surfaces (facets) represented by the unit normal and vertices using a 3D-Cartesian system"(Remarks, pp.

Art Unit: 1647

8-9). Applicant argues that the process of addition or subtraction of these layers to form the eventual structure is described, but does not take into account the eventual lay-down pattern (Remarks, p. 9). Applicant argues that the triangle facets described in the '872 patent do not describe the surface morphology of the final fabricated part, but rather the topology of the 3D shape only (Remarks, pp. 9-10). Applicant also argues that the '872 patent does not teach a structure, as instantly claimed, wherein the apparatus has a lay-down pattern forming triangular pores (Remarks, p. 10). Applicant argues that the particularly claimed lay-down patterns of instant claims 40 and 48 are more suitable for tissue engineering because such structures allow the flow transport of nutrients and wastes and have the capacity to deliver a high volume of cells (Remarks, p. 10). Applicant submits Exhibits 1-8 in support of these arguments. Applicant's arguments and exhibits (to the extent possible) have been fully considered, but they are not persuasive.

The examiner notes that submitted Exhibits 1, 7, and 8 (each one page) are darkly colored and uninterpretable. The examiner can make out the words "Tissue Engineering" on Exhibit 7, but nothing more. Applicant is advised that if these Exhibits are deemed of critical importance that color photos or printouts can be made and submitted as artifact documents. The examiner has access to and can obtain non-scanned artifact documents. This may be a more feasible way for the examiner to view the Exhibits in lieu of the darkly scanned images. Applicant is encouraged to view these exhibits in PAIR in order to better understand the image quality that the examiner is seeing.

Regarding Applicant's argument as to the uniqueness of the triangular and five-sided pore shape, the '478 patent specifically teaches that the pore or channels sizes, mechanical strength of the lattice structure, and the directional properties of the lattice structure, can readily be modified or optimized for particular applications (column 5, lines 44-47). Additionally, the '680 patent teaches that it would be desirable to control pore size, shape and tortuosity, including connectedness, during the shaping operation (column 1, line 65 to column 2, line 2). The '478, '680, and '872 patents clearly teach that the lay-down pattern and the shape of the channels and pores can be varied, depending on the design and structural needs of the maker. As stated of record, the '478 patent teaches a customized three-dimensional, layered, scaffold structure for use in tissue engineering for an individual patient including the aspect of intercrossing filaments stacked in horizontal planes (see abstract; Figures 1 and 2; Examples 1 and 2, columns 3 and 4). Interconnected pores or channels are taught at column 1, line 27. Linear components and curved components are taught in Figure 1 and column 3, line s 1-34, especially lines 33-34. Components that can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54). Thus, the

Art Unit: 1647

variations in pattern lay-down, including variations in shape from round, to triangular, or five-sided, are known variations of the prior art and they would have been predictable to one of skill in the art at the time the invention was made. The motivation to choose particular angles comes from the '478 patent, which teaches that components can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54).

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As stated of record, design incentives to vary the pattern include variance in the purpose or anatomical placement of the scaffold (for example, differences in mechanical load strength and suture pull-out strength of the scaffold would vary depending on whether the scaffold was placed in or near a weight bearing anatomical part or subjected to intense mechanical stresses), improvements in offset yield strength, or improvements in porosity that could affect blood flow or cellular influx into the scaffold. Market forces would have also prompted the need for variations due to the lack of availability of scaffolds for an increasing variety of anatomical structures and competition in the market for product designed to meet specific anatomical and mechanical repair needs. These design incentives and market forces are also evidenced by the '478 patent, the '680 patent, and the '872 patent (see i.e. the '680 patent, column 1, lines 20-28). The composition (i.e. PLC and PLC/HA) of the claimed scaffold is old and well-known in the art, as demonstrated by the '680 patent. The only difference between the instant invention and the prior art is the lay-down pattern (i.e. shape) of the melt extrusion filament used to construct the scaffold apparatus. However, the '478, '680, and '872 patents clearly teach that this pattern can be varied, depending on the design and structural needs of the maker. Thus, the variations in pattern lay-down are known variations of the prior art and they would have been readily predictable to one of skill in the art at the time the invention was made. See also, *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (holding that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant).

The claim amendments reciting the parameters for liquefier temperature are standard ranges for FDM machines (see Example 1 of the '478 patent, which teaches the claimed range). As stated of record, a porosity range of 0.2mm (200 microns) to 2mm (2000 microns) is taught at column 4, lines 11-16 of the '478 patent. It is noted that the amended pore size range constitutes new matter, as set forth below.

New Claim Rejections - Necessitated by Amendment

Claim Rejections - 35 USC § 112, First Paragraph

Written Description - New Matter

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 40 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Amended claims 40 and 48 recite a pore size range of 200-780 μ m. Claims 50 and 51 (now cancelled) recited a pore size of 200-700 μ m. A range of 200-700 μ m is taught in the specification at p. 40. A range of 250-780 μ m for channel width is taught in the specification at p. 36 (Table 1). However, a pore size range of 200-780 μ m is not taught in the specification. Applicant may not conflate different upper and lower range limits where the instantly claimed range is not specifically taught in the specification. Accordingly the amendments to claims 40 and 48 reciting a pore size range of 200-780 μ m constitutes new matter. See MPEP 2163.05 and *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), where the ranges described in the original specification included a range of “25%- 60%” and specific examples of “36%” and “50%.” A corresponding new claim limitation to “at least 35%” did not meet the description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, however a limitation to “between 35% and 60%” did meet the description requirement.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1647

14. Claims 40, 43, 59, and 60 are rejected under 35 U.S.C. 102(a) as being anticipated by Hutmacher et al., ("Design and Fabrication of a 3D Scaffold for Tissue Engineering Bone", as published in Agrawal et al., Eds *Synthetic Bioadsorbable Polymers for Implants*. ASTM, West Conchohocken, PA; May 2000, pp. 152-167).

Hutmacher et al., teach an apparatus useful in tissue engineering comprising a scaffold structure with the recited porosity (p. 156) formed from a plurality of layers of melt extrusion filament, formed in the recited temperature range (pp. 155-6). FDM is taught at p. 153. The apparatus comprising PCL is taught at p. 153. The instantly claimed lay-down pattern (triangular shaped) is taught at Table 2; pp. 155-157; p. 159; and especially Figures 3 and 4a-d. Pores are taught as readily capable of being honeycombed (hexagonal), triangular, square, or other polygonal shape (p. 159). Porosities of 48% and 61% are taught at p. 159. Pore size between 240 and 690 μm is taught at p. 159. A T16 tip is taught as producing vertical walls that are 406 μm in diameter (p. 155). Walls with a linear shape are taught at p. 155.

Conclusion

NO CLAIM IS ALLOWED.

This Office Action is NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/

Art Unit: 1647

Primary Examiner, Art Unit 1647